NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0304 NQF Project: Perinatal and Reproductive Health Project

(for Endorsement Maintenance Review)
Original Endorsement Date: Nov 15, 2007 Most Recent Endorsement Date: Nov 15, 2007

BRIEF MEASURE INFORMATION

De.1 Measure Title: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted)

Co.1.1 Measure Steward: Vermont Oxford Network

De.2 Brief Description of Measure: Standardized rate and standardized morbidity ratio for nosocomial bacterial infection after day 3 of life for very low birth weight infants, including infants with birth weights between 401 and 1500 grams and infants whose gestational age is between 22 and 29 weeks.

2a1.1 Numerator Statement: Eligible infants with one or more of the following criteria:
Criterion 1:
Bacterial Pathogen. A bacterial pathogen is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life.
OR
Criterion 2:
Coagulase Negative Staphylococcus. The infant has all 3 of the following:
1. Coagulase negative staphylococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.
2. One or more signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).
3. Teatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

2a1.4 Denominator Statement: Eligible infants who are in the reporting hospital after day 3 of life.

2a1.8 Denominator Exclusions: Exclude patients who do not meet eligibility criteria for birth weight, gestational age or hospital admission, or if the infant is discharged home, is transferred or dies prior to day 3 of life.

1.1 Measure Type: Outcome
2a1. 25-26 Data Source: Electronic Clinical Data : Registry
2a1.33 Level of Analysis: Facility

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*):
N/A

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested? Yes☐ No☐ If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): 5. Similar/related endorsed or submitted measures (*check 5.1*): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)
1a. High Impact: H☐ M☐ L☐ I ☐ (*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)
De.4 Subject/Topic Areas *(Check all the areas that apply)*: Perinatal De.5 Cross Cutting Areas (*Check all the areas that apply)*: Safety : Healthcare Associated Infections
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Severity of illness 1a.2 If "Other," please describe: 1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*: Infants admitted to neonatal intensive care units are at high risk of hospital acquired infections. Hospital acquired infection in this population is associated with increased mortality, morbidity, length of stay and cost. 1a.4 Citations for Evidence of High Impact cited in 1a.3: Reese Clark MD1,2, Richard Powers MD, Robert White MD, Barry Bloom MD, Pablo Sanchez MD and Daniel K Benjamin Jr MD, MPH, PhD. Nosocomial Infection in the NICU: A Medical Complication or Unavoidable Problem? Journal of Perinatology (2004) 24, 382–388.
1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐ (*There is a demonstrated performance gap - variability or overall less than optimal performance*)
1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure: A bundle of improvement practices has been shown to dramatically reduce the frequency of hospital acquired infections for very low birth weight infants. 1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*: [*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*] In 2009, 812 hospitals in the Vermont Oxford Network enrolled 55,006 very low birth weight infants in the Network database. 17% of these infants had a hospital acquired bacterial infection with the interquatile range among hospitals of 8% to 21%. 1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*] Vermont Oxford Network VLBW Database Summary for 2009. Vermont Oxford Network. Burlington, VT. 2010. 1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results*

for this measure by population group]
The rates vary by birth weight category ranging from 35% for infants 501 to 750 grams to 7% for infants over 1251 to 1500 grams. (Vermont Oxford Network 2009)

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Vermont Oxford Network. VLBW Database Summary 2009. Vermont Oxford Network. Burlington, VT. 2010.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I ☐ Quality: H☐ M☐ L☐ I ☐ Consistency: H☐ M☐ L☐ I ☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
Health outcome: hospital acquired bacterial infection
Process: specific practices related to hand hygiene, line insertion, care and removal
Structure: a key factor is the unit culture
Links: Unit culture impacts adherence to infection prevention practices which influence rate of infection.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Other, Selected individual studies (rather than entire body of evidence)
other

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
There is strong evidence that hospital acquired infections in the NICU can be reduced by appropriate practices and by quality improvement interventions.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: numerous

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The available studies from NICUs are observational or before after.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):*
Consistent in magnitude and direction across NICU studies and when compared to similar studies in adult and pediatric intensive care.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit*

- benefit over harms):
Marked reductions in hospital acquired bacterial infections in the NICU can be achieved leading to better outcomes, shorter hospital stay and lower costs.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: N/A

1c.13 Grade Assigned to the Body of Evidence: N/A

1c.14 Summary of Controversy/Contradictory Evidence: Given that the evidence is predominantly from before after or observational time series studies, there is the possibility that the magnitude of effect of quality improvement interventions on hospital acquired infection could be confounded by the non-randomized nature of the studies.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
Joseph Schulman, Rachel Stricof, Timothy P. Stevens, Michael Horgan, Kathleen Gase, Ian R. Holzman, Robert I. Koppel, Suhas Nafday, Kathleen Gibbs, Robert Angert, Aryeh Simmonds, Susan A. Furdon, Lisa Saiman, and the New York State Regional Perinatal Care Centers
Statewide NICU Central-Line-Associated Bloodstream Infection Rates Decline After Bundles and Checklists . Pediatrics 2011; 127:3 436-444;

David D. Wirtschafter, Richard J. Powers, Janet S. Pettit, Henry C. Lee, W. John Boscardin, Mohammad Ahmad Subeh, and Jeffrey B. Gould. Nosocomial Infection Reduction in VLBW Infants With a Statewide Quality-Improvement Model . Pediatrics 2011; 127:3 419-426

Ohio Statewide Quality-Improvement Collaborative to Reduce Late-Onset Sepsis in Preterm Infants
Heather C. Kaplan, Carole Lannon, Michele C. Walsh, Edward F. Donovan, and for the Ohio Perinatal Quality Collaborative. Pediatrics 2011; 127:3 427-435

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
See PDF below for extensive guideline recommendations
http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

1c.17 Clinical Practice Guideline Citation: Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011
http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

1c.18 National Guideline Clearinghouse or other URL: N/A

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: As in previous guidelines issued by CDC and HICPAC, each recommendation is categorized on teh basis of existing scientific data, theoretical rationale, applicability, and economic impact.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: As in previous guidelines issued by CDC and
> HICPAC, each recommendation is categorized on the basis of existing
> scientific data, theoretical rationale, applicability, and economic

> impact.
> http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

1c.23 Grade Assigned to the Recommendation: See above for CDC grading of evidence for each component of the recommendations

1c.24 Rationale for Using this Guideline Over Others:

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.vtoxford.org/about/NQF%20Measure%200304.pdf

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Eligible infants with one or more of the following criteria:
Criterion 1:
Bacterial Pathogen. A bacterial pathogen is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life.
OR
Criterion 2:
Coagulase Negative Staphylococcus. The infant has all 3 of the following:
1. Coagulase negative staphylococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.
2. One or more signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).
3. Teatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more

days.

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
After day 3 of life and until death or discharge home or transfer from the reporting hospital. Infants readmitted to the reporting hospital following transfer to another hospital are monitored following readmission.

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
Infants whose birth weight is between 401 and 1500 grams or whose gestational age is between 22 weeks 0 days and 29 weeks 6 days are included if they have coagulase negative staphylococcus or one of the bacterial pathogens listed below after day 3 of life, provided they meet one of the following criteria:
1. They are born at the reporting hospital.
OR
2. They are admitted to any location in the reporting hospital within 28 days of birth, without first having gone home.
Bacterial Pathogens List:
1. Achromobacter species [including Achromobacter xylosoxidans (also known as Alcaligenes xylosoxidans) and others]
2. Acinetobacter species
3. Aeromonas species
4. Alcaligenes species [Alcaligenes xylosoxidans and others]
5. Bacteroides species
6. Burkholderia species [Burkholderia capecia and others]
7. Campylobacter species [Campylobacter fetus, C. jejuni and others]
8. Chryseobacterium species
9. Citrobacter species [Citrobacter diversus, C. freundii, C. koseri and others]
10. Clostridium species
11. Enterobacter species [Enterobacter aerogenes, E. cloacae, and others]
12. Enterococcus species [Enterococcus faecalis (also known as Streptococcus faecalis), E.faecium, and other Enterococcus species]
13. Escherichia coli
14. Flavobacterium species
15. Haemophilus species [Haemophilus influenzae and others]
16. Klebsiella species [Klebsiella oxytoca, K. pneumoniae and others]
17. Listeria monocytogenes
18. Moraxella species [Moraxella catarrhalis (also known as Branhamella catarrhalis) and others]
19. Neisseria species [Neisseria meningitidis, N. gonorrhoeae and others]
20. Pasteurella species
21. Prevotella species
22. Proteus species [Proteus mirabilis, P. vulgaris and others]
23. Providencia species [Providencia rettgeri, and others]
24. Pseudomonas species [Pseudomonas aeruginosa and others]
25. Ralstonia species
26. Salmonella species
27. Serratia species [Serratia liquefaciens, S. marcescens and others]
28. Staphylococcus coagulase positive [aureus]
29. Stenotrophomonas maltophilia
30. Streptococcus species [including Streptococcus Group A, Streptococcus Group B, Streptococcus Group D, Streptococcus pneumoniae, Strep milleri and others]

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Eligible infants who are in the reporting hospital after day 3 of life.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Children's Health

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
After day 3 of life and within the first year of life.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Infants whose birth weight is between 401 and 1500 grams or whose gestational age is between 22 weeks 0 days and 29 weeks 6 days are included if they are in the reporting hospital after day 3 of life, provided they meet one of the following criteria:
1. They are born at the reporting hospital.
OR
2. They are admitted to any location in the reporting hospital within 28 days of birth, without first having gone home.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Exclude patients who do not meet eligibility criteria for birth weight, gestational age or hospital admission, or if the infant is discharged
home, is transferred or dies prior to day 3 of life.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
1. Any infant who meets neither of the following conditions is excluded:
   - Birth weight between 401 and 1500 grams
   - Gestational age between 22 and 29 weeks.
2. Outborn infants who are admitted to the reporting hospital more than 28 days after birth are excluded.
3. Outborn infants who have been home prior to admission to the reporting hospital are excluded.
4. Infants discharged home on or before day 3 of life are excluded.
5. Infants who die on or before day 3 of life are excluded.
6. Infants who transfer to another hospital on or before day 3 of life and who are not readmitted to the reporting hospital.
7. Infants who transfer more than once prior to day 3 of life.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
N/A

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: Statistical risk model 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
The risk adjustment process begins by using logistic regression to model the infection measure on model covariates: gestational age and its squared term, small for gestational age (Yes/No), multiple gestation (Yes/No), APGAR score at 1 minute (0-10), infant gender (Female, Male), Maternal Race/Ethnicity (Black, Hispanic, White, Asian, Other), Vaginal Delivery (Yes/No), Major Birth Defect (Yes/No) and Birth Location (Inborn, Outborn).

An estimate is made of the “systematic variation" associated with the hospital standardized morbidity ratios (SMRs) using the method suggested by Martuzzi and Hills (Martuzzi M and Hills M, Estimating the degree of heterogeneity between event rates using likelihood, Am J of Epi, 1995, 141, 4, 369-374. This method assumes that the SMRs are distributed gamma, and that deviations from the gamma distribution are associated with random variation. The systematic variation is used to “shrink” center SMR values and their confidence limits based on the number of infants reported (see, e.g., Simpson J et al, Analysing differences in clinical outcomes between hospitals, Qual Saf Health Care, 2003, 12,

257-262. The values for centers with a smaller number of infants shrink more toward the mean of all centers than do centers with more infants. Values for estimates of the number of observed cases minus the number of expected cases (O-E) and control limits for O-E values are also shrunken using the systematic variation value.
The shrinkage method described above is the "gamma-Poisson" approach to filtering random variation associated with Nosocomial Bacterial Infection as a risk adjusted indicator of performance. This approach has been used in other settings for documenting hospital performance.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:
Attachment
NQF_0304_Coef_2006_2010.xlsx

2a1.17-18. Type of Score: Other Adjusted rate and standardized morbidity ratio (observed minus expected values are also provided)

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Lower score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
1.Determine the number of infants for a reporting period (usually a birth year) who meet the population criteria described above. Be sure that all eligible infants during the reporting period are identified. This number is termed N.
2.Using the definitions in the Network Manual of Operations, determine the number of infants who had nosocomial bacterial infection after day 3 of life and prior to discharge home for each of the N infants. This is the number of eligible infants who were diagnosed as having either coagulase negative staphylococcus and/or a late bacterial pathogen after day 3 of life. The number identified as having nosocomial bacterial infection is termed the "observed number with infection" or O for short.
3.For each of the N infants, calculate the expected value of infection by multiplying the coefficient times its covariate value for each covariate (coefficients provided on request). The covariates include:
- Gestational Age in completed weeks (GA)
- GA squared
- Small for Gestational Age (data table provided on request)
- Major birth defect (0=No, 1=Yes)
- APGAR score at 1 minute (0 to 10)
- Indicator variables for maternal race or ethnicity (0 or 1)
  - Hispanic
  - Black
  - White
  - Asian
  - Other
- Birth location (0=Inborn, 1=Outborn)
- Multiple gestation (0=No, 1=Yes)
- Infant gender (0=Female, 1=Male)
- Mode of delivery (0=C-Section, 1=Vaginal)

4. Add the expected values for each of the N infants to calculate the number of expected cases of nosocomial bacterial infection. This number is termed the "expected number with infection" or E for short.

5. Calculate the standardized morbidity ratio (SMRshrnk) for nosocomial bacterial infection using the values for O and E and applying the estimate for systematic variation (v2), determined from Vermont Oxford Network analyses (provided on request).

SMRshrnk = (O + v2) / (E + v2)
with standard error SESMRshrnk=sqrt(1/(E+(1/v2)));
6. Calculate the shrunken, adjusted nosocomial bacterial infection rate (Rateshrnk) and its 95% confidence interval.
Rateshrnk = (SMRshrnk x E) / N
with standard error (SERateshrnk) equal to SESMRshrnk x E) / N .
and 95% confidence interval for Rateshrnk equal to
Rateshrnk ± 1.96 × SERateshrnk.

7. Calculate the number of observed minus expected cases of nosocomial bacterial infection, adjusting for case mix and systematic variation (O–Eshrnk), and calculate the 95% control limits for O–Eshrnk.
O–Eshrnk = E / SMRshrnk
with 95% control limits equal to O–Eshrnk ± 1.96 × SESMRshrnk x E.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
URL
http://www.vtoxford.org/about/NQF%20Measure%200304.pdf

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
Data for all eligible infants born during the reporting period are collected.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Electronic Clinical Data : Registry

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Vermont Oxford Network Database

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
http://www.vtoxford.org/about/network_db.aspx

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://www.vtoxford.org/tools/ManualofOperationsPart2.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Facility

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Hospital/Acute Care Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Infants Born between 2006 and 2010 by Nosocomial Bacterial Infection (Yes/No) and birth weight category:

	----------Birth Weight Category (grams)--------				
Infection	< 501	501-750	751-1000	1001-1250	> 1251
Yes	1793	14664	14393	8986	5949
No	2850	24659	42933	56878	80244

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Logistic regression models are tested for performance using the area under the receiver operating characteristic curve (auc). Changes in the AUC over time are monitored.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Area under ROC statistics for nosocomial bacterial infection models,
2006-2010 are shown below.

Birth Year	Area under ROC
2006	0.734
2007	0.728
2008	0.733
2009	0.723
2010	0.735

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c)* and identify any differences from the evidence:
Nosocomial bacterial bloodstream infections in neonatal intensive care units are related to increased mortality and are frequently caused by exposure to hospital staff. Risk factors include measures of prematurity (low birth weight, low gestational age and size for
gestational age) as well as such factors as low APGAR score. Monitoring of bloodstream infections is critical for improving the quality
of care (see, e.g., Tseng YC et al, Nosocomial bloodstream infection in a neonatal intensive care unit of a medical center: a threeyear
review, Journal of Microbiology, Immunology, and Infection, Sep 2002, 168-172). By taking into account risk factors associated with these infections, hospitals are given a better indication of performance. It is also important to control for random variation in performance, especially for small hospitals, since false signals can contribute to inefficient allocation of resources.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The number of hospitals submitting data for the measure, with minimum and maximum number of submitted records for eligible infants born between 2006 and 2010, are shown below.

Birth Year	Hospitals	Minimum Infants	Maximum Infants
2006	633	2	300
2007	679	1	330
2008	747	1	382
2009	813	1	312
2010	848	1	279

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Goodnes of fit for the logistic regression models are monitored over time.

The measure, including the list of bacterial pathogens, was developed by board certified neonatologists and reviewed by clinical experts in neonatal infection. The measure is reviewed annually by the Vermont Oxford Network Database Advisory Committee,consisting of national and international experts in the neonatal community. The bacterial pathogens list was last revised in 2008.

Comprehensive business rules have been implemented in software applications so that each record submitted is tested for consistency, completness and accuracy. Submitted records with errors must be corrected before data are finalized and reports of the measure are provided to hospitals.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity,*

describe results of systematic assessment):
Hosmer-Lemeshow goodnes of fit statistics for nosocomial bacterial infection models for the period 2006-2010 are shown below.

Birth Year	Fit Chi-Square
2006	36.3
2007	43.9
2008	40.6
2009	47.1
2010	41.9

The annual assessment of item definitions results in modifications to the definitions for measures collected by centers, as well as modifications to the bacterial pathogens list. Expert advisors to the registry directors provide recommendations for measure improvement and clarification of item criteria.

During data finalization, all records with errors must be corrected before reports of the measure are provided. When hospitals are unable to complete finalization, records for the birth year for that hospital are removed from the registry.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The population measured includes premature infants with birth weights between 401 and 1500 grams, as well as infants whose gestational age is between 22 and 29 weeks. The occurrence of infection is monitored after day 3 of life
while the infant is hospitalized in the reporting hospital. For infants who transfer to another hospital, monitoring continues when the infant is readmitted to the reporting hospital. Infants who are discharged home are no longer monitored. These rules for tracking infants provide a reasonably homogenous population base for performance inferences and quality improvement decisions.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Business rules require that infants be hospitalized more than three days or the measure is not applicable. Other exclusions are also enforced by business rules that assure database integrity.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
The following table shows the number of infants, number of records excluded and percent excluded for birth years 2006-2010.

Birth Year	Number of Infants	Number Excluded	Percent Excluded
2006	50,250	4,876	9.7%
2007	54,122	4,860	9.0%
2008	57,303	4,940	8.6%
2009	58,768	5,084	8.7%
2010	57,396	4,727	8.2%

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The number of hospitals and number of patients vary by birth year based on the number of hospitals participating in the registry. Each reporting hospital submits data for all eligible infants as described in the Specifications section of this submission form. The number of hospitals for the period 2006-2010 is tabulated in item 2b2.1. above. The number of infection cases for this period is tabulated in item 2b3.3. above (Number of Infants minus Number Excluded).

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
The logistic regression model includes the risk factors listed below.
- Gestational age in completed weeks and its quadratic term.
- Small for gestational age (SGA, Yes or No), defined as being in the 10th percentile or less for birth weight, given the infant's gestational age, the maternal race, the infant's gender and whether the infant was a singleton or multiple gestation. The United States Natality Datasets are used for calculating the 10th percentile values.
- Major birth defect (Yes or No).
- Multiple gestation (Yes or No).
- APGAR score at 1 minute (0 to 10).
- Infant gender (Male or Female).
- Maternal race (Hispanic, White, Asian or Other - Black is the reference category).
- Vaginal delivery (Yes or No).
- Birth location (Inborn or Outborn).

When one or more predictor variables is missing for infants with a known outcome measure, an imputation procedure is used based on Network or center specific rates for the missing values.
The adjusted rates are "shrunken" to remove random variation in signals of performance using an empirical Bayesian method. For an example of this method, see Martuzzi M and Hills M, Estimating the degree of heterogeneity between event rates using likelihood, Am J of Epi, 141, 4, 369-374 (1995) and Simpson J et al, Analysing differences in clinical outcomes between hospitals, Qual Saf
Health Care, 12, 257-262 (2003).

2b4.3 Testing Results (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
For infants born in 2010, the coefficients with standard errors and chi-square values are listed below. These values are consistents with values obtained for infants born in previous years.

Parameter	DF	Estimate	Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-7.9290	1.7004	21.7427	<.0001
GAWeeks	1	0.8195	0.1248	43.1333	<.0001
GASQ	1	-0.0208	0.00228	83.4953	<.0001
Male	1	0.1015	0.0309	10.8079	0.0010
MultipleBirth	1	0.0164	0.0357	0.2094	0.6472
Vaginal	1	-0.0140	0.0337	0.1718	0.6785
BirthDefect	1	0.5357	0.0898	35.5700	<.0001
SmallForGA	1	0.5490	0.0514	114.2164	<.0001
AP1	1	-0.0208	0.00700	8.7861	0.0030
HispRace	1	0.0677	0.0495	1.8692	0.1716
WhiteRace	1	-0.0667	0.0378	3.1091	0.0779
AsianRace	1	-0.1357	0.0845	2.5765	0.1085
OthRace	1	0.1283	0.0979	1.7177	0.1900
Outborn	1	0.1838	0.0400	21.1029	<.0001

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
In 2010 reports were sent to 850 hospitals, and the measure was applicable for 52,669 infants.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
If the 95% upper bound for the standardized morbidity ratio (SMR - observed value / expected value) is less than one, the hospital performance is classified as "better than expected"; if the 95% lower bound for the SMR is greater than one, the hospital performance is classified as "worse than expected"; if the 95% lower and upper bounds for the SMR inlcudes one, performance is classified as "as expected."

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
In 2010 52 hospitals performed better than expected, 73 perfomed better than expected and 725 perfomed as expected. Ninety-five pecent confidence limits for the estimates were used to determine statistical significance.

For the unadjusted measure, the observed rates for key percentiles are shown below for infants born in 2010 at 848 hospitals:

Percentile	Observed Percent
10th	0.0
25th	6.7
50th	11.8
75th	19.2
90th	28.6

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
N/A

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:
URL
http://www.vtoxford.org/about/NQF%20Measure%200304.pdf

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
Performance results are made available to the members of the Vermont Oxford Network at: https://nightingale.vtoxford.org Participants in the Vermont Oxford Network may access a fully featured Internet reporting system (Nightingale), as well as printed reports, which document patient characteristics, treatment practices, morbidity, mortality, and length of stay for the institution. The reports also track performance over time, comparing the institution's performance to that of the Network as a whole and with subgroups of similar institutions.

Vermont Oxford Network members may make their performance available to the public at their discretion.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: Hospital acquired infections in neonatal intensive care units are related to increased mortality, morbidity, length of stay, and cost. Measuring and reporting performance allows care providers to identify higher than expected rates of infection and opportunities for improvement of practices.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): N/A

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
Performance results are used for quality improvement by the members of the Vermont Oxford Network: http://www.vtoxford.org/about/membership.aspx. Participants in the Vermont Oxford Network may access a fully featured Internet reporting system (Nightingale), as well as printed reports, which document patient characteristics, treatment practices, morbidity, mortality, and length of stay for the institution. The reports also track performance over time, comparing the institution's performance to that of the Network as a whole and with subgroups of similar institutions.

Performance results are also used by participants in the Vermont Oxford Network's Quality Improvement Collaboratives: http://www.vtoxford.org/quality/nicq/nicq.aspx

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
There is strong evidence that hospital acquired infection in the NICU can be reduced by appropriate practices and QI interventions. Measuring and reporting performance allows care providers to identify opportunities to improve performance, and to implement practices that have been shown to reduce the frequency of hospital acquired infection.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I ☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
A manual of operations for the registry is published annually, with definitions and criterial clearly operationalized for the measure. Comprehensive business rules are implemented in software to verify records for consistency, completeness and accuracy. A definitive process is in effect to assure that the measure is not reported until data are complete and correct. Hospital contacts must verify that data for all eligible infants are submitted prior to finalization.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
Patient identifiers are not collected in the registry. Confidentiality for each hospital member is strictly maintained. Procedures in place assure reasonable confidence that data are complete and accurate. There are no specific fees for this measure, although members of the Vermont Oxford Network pay an annual membership fee.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
0478 : Neonatal Blood Stream Infection Rate (NQI #3)

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? No

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
The target population for NQF 0478 and NQF 0304 are different, as is the item definition.

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Vermont Oxford Network, 33 Kilburn St, Burlington, Vermont, 05401

Co.2 Point of Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237

Co.3 Measure Developer if different from Measure Steward: Vermont Oxford Network, 33 Kilburn St, Burlington, Vermont, 05401

Co.4 Point of Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237

Co.5 Submitter: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237, Vermont Oxford Network

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237, Vermont Oxford Network

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
N/A

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: N/A

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 10, 2011 Ad.5 What is your frequency for review/update of this measure? Annual Ad.6 When is the next scheduled review/update for this measure? 09, 2012
Ad.7 Copyright statement: Copyright © 2011 Vermont Oxford Network, Inc.
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments:
Date of Submission (*MM/DD/YY*): 10/17/2011